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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,453	11/28/2003	James C. Peacock III	53233-00007	9909

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EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	**PAPER NUMBER**
3734	

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12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/724,453	PEACOCK, JAMES C.	
	Examiner	Art Unit	
	Katherine M. Dowe	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the amendment filed 11/19/2007 after the final rejection mailed 9/18/2007.

2. Claims 1-46 are pending.

Response to Arguments

3. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

4. Applicant's arguments, see amendment after final, filed 11/19/2007, with respect to the rejection(s) of claim(s) 1-46 under Nakayama (US 2006/0036311) have been fully considered and are persuasive. Applicant argued Nakayama is not a proper 102(e) reference because the PCT was not published in English. An English translation was not filed until July 25, 2005, which is after the priority date of the instant application. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of O'Brien et al. (US 2005/0060021).

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-10, 12, 14, 15, 17-19, 29, 30, 34-37, 39, 43, and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Brien et al. (US 2005/0060021). O'Brien et al. disclose a stent (Fig 2A) comprising a scaffold from a third material (20/60), an intermediate fourth material (22/62), a porous surface (24/64) comprising a first coating material (26) having a plurality of discrete pores (27, 28), and a second composite

material comprising a plurality of particles located within each of the pores and composed of a bioactive agent (30) in combination with a bioerodible polymer material (¶0060). The pores comprise an inner diameter less than 1 micron (¶0036). The particle diameter may be defined as the inner diameter of the pore, and thus the particle diameter is less than 1 micron. The bioactive agent may comprise an anti-restenosis agent, an anti-inflammatory agent, an anti-proliferative agent, and/or a growth factor (¶0061). The first coating material may be non-polymeric electrochemically deposited material and the fourth material may be electroplated metal (¶0038, 0045). The pores are formed in the first coating material through an anodization process (¶0041).

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 11, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1 and 12 above, in view of Lye et al. (US 2004/0148015). Regarding claims 11 and 16, O'Brien disclose the invention substantially as claimed including a stent (Fig 2A) with a porous surface (24) comprising a first coating material (26) having a plurality of discrete pores (27, 28), and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent (30) in combination with a bioerodible polymer material (¶0060). However, O'Brien et al. do not disclose the first material is sintered or is inherently porous. Lye et al. disclose a similar device including

a stent with a porous surface. Lye et al. teach porous materials are commonly used in medical implants as matrices for the retention of therapeutic agents. Such materials include ceramics and sintered metal powders (¶0003). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the first material included an inherently porous material, such as a sintered material, to simplify the manufacturing process by eliminating the step of forming the pores by anodization.

Regarding claim 13, O'Brien discloses the invention substantially as claimed including a stent with a first coating material that is not inherently porous. However, O'Brien discloses the pores are formed by anodization (¶0041) and do not disclose forming the pores by laser cutting the first material. Lye et al. disclose a similar device including a stent with a porous surface. Lye et al. teach the porous layer may be formed by a variety of methods including laser cutting (¶0020). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the pores were formed by laser cutting the first material to easily form the pores in a specific reproducible pattern.

8. Claims 20-28, 31-33, 45, and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 19 above, in view of Gertner et al. (US 2003/0060873). O'Brien et al. disclose the invention substantially as claimed including a stent (Fig 2A) comprising a scaffold from a third material (20/60), an intermediate fourth material (22/62), a porous surface (24/64)

comprising a first coating material (26) having a plurality of discrete pores (27, 28), and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent (30) in combination with a bioerodible polymer material (¶0060). The pores comprise an inner diameter less than 1 micron (¶0036). The particle diameter may be defined as the inner diameter of the pore, and thus the particle diameter is less than 1 micron. The bioactive agent may comprise an anti-restenosis agent, an anti-inflammatory agent, an anti-proliferative agent, and/or a growth factor (¶0061). The third material forming the stent scaffold may comprise a stainless steel alloy, a nickel-titanium alloy, or a cobalt-chromium alloy (¶0065). The first coating material may be non-polymeric electrochemically deposited material and the fourth material may be electroplated metal (¶0038, 0045).

Regarding claims 20-28, 45, and 46, O'Brien et al. disclose the pores are formed in the first coating material through an anodization process (¶0041). However, O'Brien et al. do not disclose the electrochemically deposited material is an electrolessly electrochemically deposited material including a composite with a metal and a reducing agent of that metal. Gertner et al. disclose a similar device including a stent comprising a scaffold, a porous surface on the stent comprising a first material and a plurality of pores, and a second material comprising a bioactive agent located within the pores using an alternate first material. The first material is an electrolessly electrochemically deposited metallic matrix (¶0048) and thus comprises a metal and a reducing agent of the metal (¶ 0036, 0057). The metal may comprise nickel or cobalt and the reducing agent may comprise phosphorus (¶ 0056, 0064). Therefore, it would have been

obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the first material was composed of an electrolessly deposited material such as nickel or cobalt with phosphorous. Gertner et al. disclose it is difficult to fully incorporate bioactive agents into structures that have previously had pores formed therein (¶0009). Alternatively, by forming the first porous material by electroless electrochemical deposition, the bioactive material can be stored in the pores at a greater concentration (¶0041). Thus, this method would allow the O'Brien et al. device to incorporate a greater concentration of bioactive material to improve the drug delivering capacity of the device.

Regarding claims 31-33, O'Brien et al. disclose an intermediate fourth material (22/62) between the first material and the third material. However, O'Brien et al. do not disclose a fifth material between the fourth material and the first coating material. Gertner et al. teach a fourth material may be formed between the stent, or third material, and the coating, or second material, and a fifth material may be formed between the fourth material and the coating, or second material, since a plurality of layers may be formed with coating layers between metallic layers (¶0063). The fourth material may be electroplated metal such as nickel (¶0029, 0036, 0064), the fifth material may be a layer of electrolessly electrochemically deposited composite with metal and a reducing agent of the metal (¶0056-0058), and the coating, or first material, may be another layer of electrolessly electrochemically deposited composite with metal and reducing agent of the metal with the composite material (¶0051). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

device of O'Brien et al. such that the stent system comprised a fourth layer of electroplated nickel and a fifth layer of electrolessly electrochemically deposited material comprising a metal and its reducing agent between the stent, or third material, and the second material. Furthermore, it would have been obvious to modify the first coating material such that it was composed of an electrolessly electrochemically deposited material comprising a metal and its reducing agent. The additional layers would provide additional pores to provide a greater amount of bioactive agent. Furthermore, the electroless electrochemical deposition would allow the O'Brien et al. device to incorporate a greater concentration of bioactive material in each pore to improve the drug delivering capacity of the device.

9. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1 above, in view of Wang et al. (US 2007/0037739). O'Brien et al. disclose the invention substantially as claimed including a stent comprising a scaffold from a third material (20), a porous surface (24) comprising a first material (26) and having a plurality of pores (27, 28), and a second composite material comprising a plurality of particles located within each of the pores and composed of a bioactive agent (30) in combination with a bioerodible material (¶0060). Furthermore, the bioactive agent may comprise an anti-restenosis agent, anti-inflammatory agent, anti-proliferative agent, or growth factor (¶0061). However, O'Brien et al. do not disclose the bioactive agent may comprise des-aspartate angiotensin 1. Wang et al. disclose compounds useful in coating stents to treat restenosis including

des-aspartate angiotensin 1 (¶0040, 0253-0261) which has been shown to substantially inhibit smooth muscle cell proliferation and drastically reduce restenosis (¶0261). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Nakayama such that the bioactive agent may also comprise des-aspartate angiotensin 1. Thus, the marketability of the device would increase and the stent may be more effective by effectively reducing restenosis.

10. Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien et al. (US 2005/0060021), as applied to claim 1 above. O'Brien et al. disclose the second composite material located within the pores is composed of a bioerodible polymer material in combination with a bioactive agent (¶0060). However, O'Brien et al. do not disclose the ratio of bioactive material to bioerodible material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Brien et al. such that the second composite material was formed with a ratio of bioactive material to bioerodible material to be at least 0.5:1, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
December 4, 2007

Todd E. Manahan
SPE 3734